

We Claim:

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1. An assembly for introducing a closure material to seal a puncture site in a blood vessel, the closure material comprising a mixture of first and second components which, upon mixing, react to form a solid closure material composition, the assembly comprising

5 a catheter for passage through a tissue puncture track and having a distal end, at least one nozzle located adjacent the distal end, and a catheter lumen in the catheter to convey the first and second components for

10 dispensing through the at least one nozzle, and

a structure carried by the catheter distal to the at least one nozzle and being arranged for expansion within the blood vessel to resist outward passage through the puncture site and to thereby locate the at least one nozzle

15 outside the blood vessel adjacent the puncture site, the structure comprising an open configuration allowing blood flow through the structure.

2. An assembly according to claim 1

wherein the catheter is sized to block flow of fluid from the nozzle into a substantial part of the tissue puncture, whereby the solid closure material composition

5 forms a localized in situ closure adjacent the vessel puncture site to seal the vessel puncture site.

3. An assembly according to claim 1

further including a mechanism to operate the structure between a collapsed condition, permitting passage through the puncture site into the blood vessel, and an

5 expanded condition, resisting passage through the puncture site.

4. An assembly according to claim 3

wherein the mechanism includes an element to selectively lock the structure in a desired expanded, collapsed, or intermediate condition.

5. An assembly according to claim 1

further including an introducer assembly adapted to communicate with the catheter lumen for dispensing the first and second components into the catheter lumen.

6. An assembly according to claim 5 wherein the introducer assembly includes an air vent.

7. An assembly according to claim 5 wherein the introducer assembly includes a mixing chamber to bring the first and second components into a mixed condition before entering the catheter lumen.

8. An assembly according to claim 5 wherein the introducer assembly includes a closure composition test chamber.

9. An introducer assembly for conveying a closure material into a catheter to seal a puncture site in a blood vessel, the closure material comprising a mixture of first and second components which, upon mixing, undergo a reaction to form a solid closure material composition, the introducer assembly comprising

a fluid path adapted at one end to be coupled to one or more dispensers containing the first and second compositions and adapted at another end to be coupled to the catheter,

a mixing chamber in the fluid path to bring the first and second components into a mixed condition before entering the catheter, and

a composition test chamber in a downstream flow direction from the mixing chamber to retain a residual volume of the first and second components in the mixed condition while another volume of the first and second components enter the catheter in the mixed condition.

10. An introducer assembly according to claim 9 wherein the composition test chamber comprises a flexible pouch-like structure enclosing the residual volume, whereby the reaction forming the solid closure material

5 composition can be tactilely gauged.

11. An introducer assembly according to claim 9
wherein the composition test chamber comprises a
transparent structure enclosing the residual volume, whereby
the reaction forming the solid closure material composition
5 can be visually gauged.

12. An introducer assembly according to claim 9
further including an air vent in the fluid path.

~~13.~~ A formative component assembly to house a
closure material, which, in use, is dispensed to seal a
puncture site in a blood vessel, the closure material
comprising a mixture of first and second components which,
5 upon mixing, undergo a reaction to form a solid closure
material composition, the formative component assembly
comprising

a barrel having an applicator end and a dispensing
end,

10 a plunger on the applicator end for advancement
into the barrel toward the dispensing end,

an internal barrier within the barrel dividing the
barrel into a first compartment adjacent the applicator end,
which houses the first component prior to use, and a second
15 compartment adjacent the dispensing end, which houses the
second component prior to use,

a valve element in the barrier operating, in
response to advancement of the plunger toward the dispensing
end, to dispense the first component from the first
20 compartment into the second compartment to form a mixture of
the first and second components in the second compartment,
the advancement of the plunger further operating to dispense
the mixture from the dispensing end.

14. A formative component assembly according to
claim 13

wherein the first compartment houses the first
component in a liquid form.

15. A formative component assembly according to claim 13

wherein the second compartment houses the second component in a solid form.

16. A formative component assembly according to claim 15

wherein the second component is in a lyophilized form.

17. A formative component assembly according to claim 13

wherein the valve element comprises a check valve permitting flow from the first compartment to the second compartment and not vice versa.

18. A formative component assembly according to claim 13

wherein advancement of the plunger to dispense the first component from the first compartment into the second compartment brings the plunger into contact with the barrier, and

wherein the barrier is carried for advancement toward the dispensing end in tandem with the plunger after the contact occurs to dispense the mixture from the dispensing end.

19. A formative component assembly to house a closure material, which, in use, is dispensed to seal a puncture site in a blood vessel, the closure material comprising a mixture of first and second components which, upon mixing, undergo a reaction to form a solid closure material composition, the formative component assembly comprising

a barrel having an applicator end and a dispensing end,

a mixing chamber in the dispensing end, which houses the second component prior to use, the mixing chamber including a barrier movable within the mixing chamber in

response to hydraulic pressure,

15 a diluent chamber in the actuator end mounted for advancement in the barrel toward the dispensing end, the diluent chamber housing the first component prior to use, a plunger mounted for advancement into the diluent chamber, and

20 a needle valve element communicating with the diluent chamber, the needle valve element passing through the barrier and entering the mixing chamber in response to advancement of the plunger that advances the diluent chamber toward the dispensing end, to thereby dispense the first component from the diluent chamber through the barrier and
25 into the mixing chamber, to form a mixture of the first and second components in the mixing chamber, the subsequent advancement of the plunger further operating to affect movement of the barrier away from the dispensing end in response to hydraulic pressure to accommodate an increasing
30 volume of the mixture in the mixing chamber, bringing the barrier into contact with the diluent chamber, wherein the barrier is subsequently carried for advancement toward the dispensing end in tandem with the plunger after the contact occurs to dispense the mixture from the dispensing end.

20. A formative component assembly according to claim 19

wherein the diluent chamber houses the first component in a liquid form.

21. A formative component assembly according to claim 19

wherein the mixing chamber houses the second component in a solid form.

22. A formative component assembly according to claim 21

wherein the second component is in a lyophilized form.

23. A method for introducing a closure material

to seal a puncture site in a blood vessel, the closure material comprising a mixture of first and second components which, upon mixing, react to form a solid closure material composition, the method comprising the steps of

5 providing a catheter having a distal end, at least one nozzle located adjacent the distal end, a catheter lumen in the catheter to convey the first and second components for dispensing through the at least one nozzle, and an
10 expandable structure carried on the catheter distal to the at least one nozzle, the structure comprising an open configuration allowing blood flow through the structure,

deploying the catheter through a tissue puncture track to locate the structure within the blood vessel,

15 expanding the structure within the blood vessel to resist its outward passage through the puncture site, and

locating the at least one nozzle outside the blood vessel adjacent the puncture site by pulling on the catheter to bring the expanded structure in contact with an interior
20 wall of the blood vessel.

24. A method for conveying a closure material into a catheter to seal a puncture site in a blood vessel, the closure material comprising a mixture of first and second components which, upon mixing, undergo a reaction to
5 form a solid closure material composition, the method comprising the steps of

establishing a fluid path communicating at one end with one or more dispensers containing the first and second compositions and at another end with the catheter,

10 bringing the first and second components into a mixed condition in the fluid path before entering the catheter, and

15 retaining a residual volume of the first and second components in the mixed condition within a composition test chamber located in the fluid path while allowing another volume of the first and second components

to enter the catheter in the mixed condition,
monitoring the reaction forming the solid closure
material with reference to the residual volume retained in
the composition test chamber.

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25. A method according to claim 24

wherein the composition test chamber comprises a
transparent structure enclosing the residual volume, whereby
the reaction forming the solid closure material composition
can be visually gauged.

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26. A method according to claim 24

wherein the composition test chamber comprises a
flexible pouch-like structure enclosing the residual volume,
whereby the reaction forming the solid closure material
composition can be tactilely gauged.

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27. A method according to claim 24

further including the step of venting air in the
fluid path.

28. A method of dispensing a closure material to
seal a puncture site in a blood vessel, the closure material
comprising a mixture of first and second components which,
upon mixing, undergo a reaction to form a solid closure
material composition, the method comprising the steps of

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providing a barrel having an applicator end and a
dispensing end, a plunger on the applicator end for
advancement into the barrel toward the dispensing end, and
first and second compartments formed within the barrel,

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housing the first component prior to use in one of
the first and second compartments,

housing the second component prior to use in the
other one of the first and second compartments,

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operating the plunger in a first advancement mode
toward the dispensing end to dispense the first component
from the one compartment into the other compartment to form
a mixture of the first and second components within the
other compartment, and

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operating the plunger in a second advancement mode
to dispense the mixture from the dispensing end.

29. A method according to claim 28
wherein the first component is housed in a liquid
form.

30. A method according to claim 29
wherein the second component is housed in a solid
form.

31. A method according to claim 30
wherein the second component is housed in a
lyophilized form.